

08 CV 02339

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

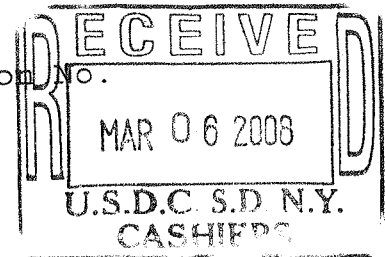
-----X  
LEOTA L. BALCH,  
  
Plaintiff,  
  
v.  
  
NOVARTIS PHARMACEUTICALS  
CORPORATION,  
  
Defendant.  
-----X

Civil Action No.

08 CV \_\_\_\_\_

COMPLAINT

JURY TRIAL DEMANDED



Plaintiff Leota L. Balch ("Plaintiff"), by her attorneys,  
for her Complaint against defendant Novartis Pharmaceuticals  
Corporation ("Novartis" or "Defendant"), alleges:

1. This is a civil action for damages suffered by  
Plaintiff as a result of her being prescribed and injected with  
Defendant's drugs Aredia and Zometa.

PARTIES

2. Plaintiff is a citizen and resident of the State of  
Oregon, residing in Portland, Oregon.

3. At all times herein mentioned, Defendant was and is a Delaware corporation, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

4. At all times herein mentioned, Defendant did business in the States of New York and Oregon.

#### JURISDICTION

5. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars (\$75,000.00) and Plaintiff is a citizen of a State which is different from the State where defendant is incorporated and has its principal place of business.

#### FACTUAL BACKGROUND

6. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

7. Aredia is the brand name of pamidronate and Zometa is the brand name of zoledronic acid, both are in a class of prescription drugs called bisphosphonates. Aredia and Zometa are administered intravenously and/or by injection.

8. Aredia and Zometa were approved by the United States Food and Drug Administration for treatment of hypercalcemia and bone metastases.

9. The product literature prepared by Novartis and circulated to physicians for use in prescribing the drugs contained no warning about osteonecrosis of the jaw or other bone structure.

10. In 2002 or before, Defendant received information from a physician that several of the physician's patients who were given Aredia were diagnosed with osteonecrosis of the jaw and that he believed a causal relationship existed between the use of Aredia and osteonecrosis of the jaw.

11. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia and Zometa. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

12. Defendant sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of Aredia and Zometa in September 2004 and May 2005.

13. Plaintiff was prescribed and given Aredia and Zometa.

14. As a result of being given and/or injected with Aredia and Zometa, Plaintiff developed osteonecrosis of the jaw.

15. As a result of being given and/or injected with Aredia and Zometa Plaintiff suffered compensable injuries, including but not limited to the following:

- a. severe and permanent physical and medical injuries and associated disabilities;
- b. severe past and future pain and suffering;
- c. severe past and future mental anguish;
- d. loss of enjoyment of life;
- e. increased risk of health problems;
- f. past and future medical care and monitoring; and
- g. loss of past and future income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

16. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

17. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

18. Aredia and Zometa as designed, manufactured and sold by Defendant were defective in design or formulation in that they were unreasonably dangerous.

19. Aredia and Zometa as designed, manufactured and sold by Defendant were defective in design or formulation in that their foreseeable risks exceeded the benefits associated with the design or formulation.

20. Aredia and Zometa as designed, manufactured and sold by Defendant were defective due to inadequate warnings because Defendant knew or should have known that the products created a risk of harm to consumers.

21. Aredia and Zometa as designed, manufactured and sold by Defendant were defective due to inadequate testing.

22. As the proximate cause and result of the defective condition of Aredia and Zometa as designed, manufactured and sold by Defendant, Plaintiff was injured.

**SECOND CLAIM FOR RELIEF**

**[Strict Product Liability - Failure To Warn]**

23. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

24. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

25. Aredia and Zometa as designed, manufactured and sold by Defendant were not accompanied by proper warnings regarding possible adverse side effects.

26. Defendant knew or should have known about the possible adverse side effects of Aredia and Zometa, including osteonecrosis of the jaw.

27. As the proximate cause and result of Defendant's failure to properly warn physicians and consumers, Plaintiff was injured.

THIRD CLAIM FOR RELIEF

[Negligence]

28. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

29. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

30. Defendant had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia and Zometa, including a duty to

assure that users, like Plaintiff, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

31. Defendant failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia and Zometa in that Defendant knew or should have known that Aredia and Zometa created an unreasonable risk of osteonecrosis of the jaw.

32. Defendant was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia and Zometa.

33. As the proximate cause and result of Defendant's negligence, Plaintiff was injured.

**FOURTH CLAIM FOR RELIEF**

**[Breach of Express Warranty]**

34. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

35. Defendant expressly warranted, by and through statements made by Defendant or its authorized agents, that Aredia and Zometa were safe, effective, and fit for their intended use.

36. Plaintiff, and her agents, relied on the skill, judgment and representations of Defendant.

37. Aredia and Zometa did not conform to Defendant's express warranties in that they were not safe and fit for their intended use because they caused serious adverse side effects, including osteonecrosis of the jaw.

38. As the proximate cause and result of Defendant's breach of its express warranties, Plaintiff was injured.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

39. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

40. Defendant impliedly warranted to Plaintiff, and her agents, that Aredia and Zometa were of merchantable quality and were safe and fit for their intended use.

41. Plaintiff, and her agents, relied on Defendant's skill and judgment.

42. Aredia and Zometa were not of merchantable quality or safe and fit for their intended use in that they caused serious adverse side effects, including osteonecrosis of the jaw.

43. As the proximate cause and result of Defendant's breach of its implied warranties, Plaintiff was injured.



PRAYER FOR RELIEF

WHEREFORE, plaintiff Leota L. Balch respectfully prays for relief and judgment against the defendant as follows:

(a) compensatory damages in an amount to be determined at trial;

(b) attorneys' fees, expenses, and costs of this action; and

(c) for any other relief this Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Dated: New York, New York  
February 15, 2008

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